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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,368	10/27/2000	Thomas N. Metcalf III	33377-00	6981

7590 06/21/2006

Alan M Gordon
American Home Products Corporation
Patent Law Department
One Campus Drive
Parsippany, NJ 07054

EXAMINER	
GANGLE, BRIAN J	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 06/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/674,368	METCALF III ET AL.	
	Examiner	Art Unit	
	Brian J. Gangle	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 October 2000*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-42* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-2 and 7-8, drawn to vaccine compositions comprising a *Neisseria gonorrhoeae* pilin protein.

Group II, claim(s) 1, 3-4, and 7-8, drawn to vaccine compositions comprising a *Neisseria meningitidis* class I pilin protein.

Group III, claim(s) 1, 3, 5, and 7-8, drawn to vaccine compositions comprising a *Neisseria meningitidis* class II pilin protein.

Group IV, claim(s) 6 and 27, drawn to vaccine compositions comprising a chimeric protein of a *Neisseria gonorrhoeae* pilin protein and SEQ ID NO:2.

Group V, claim(s) 9, drawn to a method of immunizing against *Neisseria gonorrhoeae* using a vaccine composition comprising a *Neisseria gonorrhoeae* pilin protein.

Group VI, claim(s) 10, drawn to a method of immunizing against *Neisseria gonorrhoeae* using a vaccine composition comprising a *Neisseria meningitidis* class I pilin protein.

Group VII, claim(s) 11, drawn to a method of immunizing against *Neisseria gonorrhoeae* using a vaccine composition comprising a chimeric protein of a *Neisseria gonorrhoeae* pilin protein and SEQ ID NO:2.

Group VIII, claim(s) 12, drawn to a method of immunizing against *Neisseria meningitidis* using a vaccine composition comprising a *Neisseria meningitidis* class I pilin protein.

Group IX, claim(s) 13, drawn to a method of immunizing against *Neisseria meningitidis* using a vaccine composition comprising a *Neisseria gonorrhoeae* pilin protein.

Group X, claim(s) 14, drawn to a method of immunizing against *Neisseria meningitidis* using a vaccine composition comprising a chimeric protein of a *Neisseria gonorrhoeae* pilin protein and SEQ ID NO:2.

Group XI, claim(s) 15, drawn to a method of preparing a vaccine comprising a *Neisseria* pilin protein.

Group XII, claim(s) 16-26, drawn to DNA encoding a chimeric protein of a *Neisseria gonorrhoeae* pilin protein and SEQ ID NO:2, plasmids comprising said DNA, host cells comprising said plasmid, and a method of producing said protein by culturing said host cell.

Group XIII, claim(s) 28 and 42, drawn to vaccine compositions comprising a chimeric protein of a *Neisseria gonorrhoeae* pilin protein and SEQ ID NO:4.

Group XIV, claim(s) 29, drawn to a method of immunizing against *Neisseria gonorrhoeae* using a vaccine composition comprising a chimeric protein of a *Neisseria gonorrhoeae* pilin protein and SEQ ID NO:4.

Group XV, claim(s) 30, drawn to a method of immunizing against *Neisseria meningitidis* using a vaccine composition comprising a chimeric protein of a *Neisseria gonorrhoeae* pilin protein and SEQ ID NO:4.

Group XVI, claim(s) 31-41, drawn to DNA encoding a chimeric protein of a *Neisseria gonorrhoeae* pilin protein and SEQ ID NO:4, plasmids comprising said DNA, host cells comprising said plasmid, and a method of producing said protein by culturing said host cell.

The inventions listed as Groups I-XVI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking groups I-XVI appears to be a vaccine composition comprising an isolated and purified recombinantly expressed pilin protein of the genus *Neisseria*.

However, Rothbard *et al.* (J. Exp. Med., 160:208-221, 1984) disclose an immunogenic composition containing *Neisseria gonorrhoeae* pili (see page 209, paragraph 3). The products of the prior art reference appear to be the same as the product claimed by the applicant because they appear to possess the same or similar functional characteristics, i.e. an immunogenic composition and a vaccine comprising *Neisseria gonorrhoeae* pilin proteins. The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPQ 964 (CAFC 1985); In re Marosi, 218 USPQ 289, 29222-293 (CAFC 1983); In re Brown, 173 USPQ 685 (CCPA 1972). Therefore, Rothbard *et al.* meets the limitations of claim 1.

Therefore, the technical feature linking the inventions of groups I-XVI does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the art.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and

specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Gangle whose telephone number is (571) 272-1181. The examiner can normally be reached on M-F 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brian Gangle
6/8/2006

ROBERT ZEMAN
PATENT EXAMINER